Remarks

Claims 13, 27, 29, and 33 have been amended. Claims 13-19, 24, 27, 29, 33, 34, 36-39, 41, 43, and 44 are pending. Applicants respectfully requests reconsideration by the Examiner in light of previously presented amendments and the following remarks.

Support for the amended claims 13, 27. 29, and 33 can be found in the specification, for example, at page 7, lines 17-19; page 12, lines 14-16; and page 12, lines 18-23.

Claim Rejections - 35 USC § 102(b)

(1) Claims 13, 15, 16, 24, 27, 29, 33, 34, 36, 39, and 41 stand rejected under 35 U.S.C. 102(b) as the claims are said being unpatentable over Helmus et al (US 5,447,724).

In the present office action, the Examiner has rejected claims 13, 15, 16, 24, 27, 29, 33, 34, 36, 39 and 41 as being anticipated by Helmus et al. (U.S. 5,447,724). The Examiner has suggested that Helmus et al. teach an implantable medical device (col. 3, lines 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as heparin (col. 6, line 51) or a steroid (col. 6, line 56) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46), wherein the drug makes up 2% by weight of the material (col. 7, lines 57-62).

"For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990) "Anticipation under 35 U.S.C. § 102 (b) requires the presence in a single prior art disclosure of each and every element of a Claimed invention." Electro Medical Systems, S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994). "[O]ne who seeks such a finding must show that each element of the Claim in issue is found, either expressly or under principles of inherency, in a single prior art reference, or that the Claimed invention was previously known or embodied a single prior art device or practice." Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 24 U.S.P.Q.2d 1321, 1326 (Fed. Cir. 1992).

The above-mentioned claims of the present application provide claim limitations that are not disclosed or suggested in Helmus et al. and therefore the criteria for a rejection pursuant to 35 U.S.C. §102(b) have not been satisfied. For example, claims 13, 27, 29, and 33 (and the related dependent claims) include

limitations that: 1) the tissue-contacting surface of the elongate body consists essentially of a non-porous polymer in intimate contact at the tissue-contacting surface with a steroidal anti-inflammatory agent; and 2) where the anti-inflammatory agent is in a concentration effective for modulating degradation or tissue encapsulation of said catheter.

Applicants respectfully disagree that the cited reference teaches what is claimed. Applicants' claims are directed to a catheter having a tissue-contacting surface consisting essentially of a non-porous polymer in "intimate contact" at the tissue-contacting surface with an anti-inflammatory agent. Helmus et al. teach a porous drug release system wherein a physiologically active agent is released through pores formed in the polymer and does not require that the tissue-contacting surface of the polymer be in intimate contact with the physiologically active agent. Helmus et al. use poragens to form pores in the polymer that serve as reservoirs for the agent. Helmus et al. also use these pores as the major mechanism for drug release. The pores can be created either by an added elutable component or the active agent itself. However, the fact that the agent and the polymer may be mixed does not necessarily result in the agent being in intimate contact with the tissue-contacting surface.

Moreover, the claims of the present invention include the limitation that the anti-inflammatory agent be present in a concentration or amount effective for modulating degradation or tissue encapsulation of the catheter. Helmus et al. teach a porous drug release system where the physiologically active agent has a beneficial effect but does not suggest that such beneficial effect be modulation of degradation or tissue encapsulation of the catheter and does not teach that the amount of such agent be effective for such purposes.

Claim Rejections - 35 USC § 103

(1) Claims 37, and 43 stand rejected under 35 U.S.C. 103(a) as the claims are said being unpatentable over Helmus et al (US 5,447,724).

The rejection notes that Helmus et al. teach all the claimed subject matter except for the slightly lower concentrations in claims 37 and 43. Helmus et al. was also cited for teaching 2% of the material is the drug, whereas the (present) claims call for a maximum of 1%. The rejection further states that in a tissue-contacting wall of a catheter, the amounts of a drug that are needed to achieve a desired release rate vary somewhat based on the specific material that the drug is being mixed into, and

also how the catheter was formed (i.e. extrusion process, etc.). The Examiner then took the position that it would have been obvious to one of ordinary skill in the art to vary the weight percentage of a drug such a small amount in order to achieve a desired release rate depending the polymer being used and the manufacturing on process (temperature, curing, etc) used to make the catheter.

Applicants respectfully traverse. Helmus et al. teach that the elutable component in the outer layer may be a physiologically active agent (col. 7, lines 57-59). However, such agent is released into the surrounding tissue and is not required to modulate degradation or tissue encapsulation of the catheter. Absent Applicants' invention that the use of a steroidal anti-inflammatory agent in intimate contact with the tissue-contacting surface of the catheter would be desirable, one of ordinary skill in the art would not be motivated to vary the weight percentage of a drug. More particularly, it is preferred by Helmus et al. to incorporate, as stated in the specification, "a minor amount, for example, about 2% by weight (col. 7, lines 60-62)." The 0.1% - 1% agent in the present claims equates to 50% to 95% below Helmus' teaching. It does not appear to be obvious to one of ordinary skill in the art to reduce the agent by 50% to 95% when the 2% has already been stated as "a minor amount."

Furthermore, as discussed above and also noted in the rejection, the agent in Helmus' outer layer is there to form pores and passages. It would not be obvious to one of ordinary skill in the art nor is there incentive to modify the 2% content.

Even more, the amended claims 13 and 29 would render claims 37 and 43 further unobvious over Helmus et al. (US 5,447,724), which does not disclose a catheter having a tissue-contacting surface comprising a non-porous polymer having a physiologically active agent in intimate contact with the tissue-contacting surface wherein the agent is in a concentration effective for modulating degradation or tissue encapsulation of an indwelling catheter. Applicants thus submit that the rejection of claims 37 and 43 under 35 U.S.C. §103(a) should be withdrawn.

(2) Claim 14 stands rejected under 35 U.S.C. 103(a) as the claim is said being unpatentable over Chait (US 5,727,555) in view of Helmus et al (US 5,447,724).

Chait was cited for teaching a catheter having an external fitting coupled to the proximal end, and helical coils as claimed. However, Chait lacks a layer with anti-inflammatory agent in it. Helmus et al. was found to teach an elongate body-inserted member with an anti-inflammatory agent imbedded in the tissue-contacting surface as

discussed supra. The rejection then contended that it would have been obvious to one having ordinary skill in the art to form the catheter of Chait with the layered structure of Helmus in order to reduce inflammation in the treatment area, since formation of catheters with layers and with drug-saturated layers is well known in the art of catheters.

Applicants respectfully traverse. With regards to a rejection pursuant to 35 U.S.C. §103, the Examiner bears the initial burden in establishing a prima facie case of obviousness when rejecting claims under 35 U.S.C. §103. In re Piasecki, 745 F.2d 1468, 223 USPQ 758 (Fed. Cir. 1985); In re Reuter, 651 F.2d 751, 210 USPQ 249 (CCPA 1981). If the Examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of non-obviousness.

To properly establish a prima facie case of obviousness, MPEP § 706.02(j) identifies three basic criteria that must be met. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. Second, there must be some suggestion or motivation in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine reference teachings. Finally, there must be a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). The mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *See* MPEP 2143.01, citing *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000)

First as discussed above, even if Helmus et al. and Chait were properly combined the prior art references do not teach or suggest all of the claim limitations of the pending claims. Neither Helmus et al. nor Chait teach or suggest that a catheter have a tissue-contacting surface consisting essentially of a non-porous polymer in intimate contact with a steroidal anti-inflammatory agent at the tissue-contacting surface. Also, neither reference suggests that the anti-inflammatory agent be present in an amount effective for modulating degradation or tissue encapsulation of an indwelling catheter.

Furthermore, there is no motivation to combine the references. Chait teaches a catheter having an external fitting coupled to the proximal end and helical coils, said helical coils to be reformed against an interior surface of the body cavity (col. 2, lines 10-24), and intends to solve the problem of accidental dislodge during application (abstract). Chait does not teach or suggest use of the active agent in intimate contact

with a non-porous polymer at the tissue-contacting surface of the catheter, in its catheter having helical coils. In comparison, Helmus et al. teach using physiologically active agents to prevent adverse reactions to the device, but does not teach or suggest use helical coils to prevent dislodge of the device. Therefore, there is no suggestion or incentive for modifying Chait, Helmus et al., or combination of two to form Applicants' claim 14. Applicants thus submit that the rejection of claims 14 under 35 U.S.C. §103(a) should be withdrawn.

(3) Claims 17-19, 38, and 44 stand rejected under 35 U.S.C. 103(a) as the claims are said being unpatentable over Helmus et al (US 5,447,724) in view of Fearnot et al. (US 5,609,629).

Helmus et al. was cited for teaching all the claimed subject matter except for the steroid being a glucocortiocosteroid such as dexamethasone. Fearnot et al. was cited for teaching the use of dexamethasone in a drug embedded outer layer of a catheter. The rejection then contended that it would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot et al. as one of the steroids broadly mentioned by Helmus et al. (col. 6, line 56) since dexamethasone is a well known anti-inflammatory steroid, and as demonstrated by Helmus et al. it is known to use it as the bioactive component of a bioactive surface on a catheter.

Applicants again respectfully traverse. First as discussed above, even if Helmus et al. and Fearnot et al. were properly combined the prior art references do not teach or suggest all of the claim limitations of the pending claims. Neither Helmus et al. nor Fearnot et al. teach or suggest that a catheter have a tissue-contacting surface consisting essentially of a non-porous polymer in intimate contact with a steroidal anti-inflammatory agent at the tissue-contacting surface. Also, neither reference suggests that the anti-inflammatory agent be present in an amount effective for modulating degradation or tissue encapsulation of an indwelling catheter.

Also, the mere fact that references can be combined or modified does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *See* MPEP 2143.01, citing *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). The proposed modification cannot change the principle of operation of a reference. MPEP 2143.01 citing *In re Ratti*, 270 F.2d 810 (CCPA 1959).

As mentioned above, the principle of operation of Helmus' outer layer, even if a physiologically active agent (e.g., glucocorticosteroid) shall be used, consists of

creating pores for passages, so that the agent may be released not to create a bioactive surface on the catheter. Likewise, the principle of operation of Fearnot et al. is to use a porous coating layer over a bioactive layer. To obtain the catheter of the present claims the porous polymer of Fearnot et al. would need to be replaced with a non-porous polymer, which would change the nature of the Fearnot et al. invention. Moreover, as Helmus et al. teaches the use of a porous release system there is no motivation in the references to combine them in a manner that would result in a tissue-contacting surface consisting essentially of a non-porous polymer.

Additionally, the amended claims 13 and 29 would render claims 17-19, 38, and 44 further unobvious over Helmus et al. (US 5,447,724) in view of Fearnot et al. (US 5,609,629), as neither reference teaches modulating degradation or tissue encapsulation of an indwelling catheter. Applications thus submit that the rejection of claims 17-19, 38, and 44 under 35 U.S.C. §103(a) should be withdrawn.

Summary

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

Respectfully submitted,

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